

REMARKS

Claims 1-20, 24-45, 47, and 48 are presented for consideration by the Examiner. Claims 21-23 and 46 have been canceled due to a restriction requirement, and every ground of rejection has been addressed.

New dependent claims 47 and 48 have been added. The subject matter in claims 47 and 48 is supported in the disclosure, *inter alia*, reference numeral 68 in FIGS. 4 and 5, and is therefore not new matter.

Applicants note with appreciation the indication of allowable subject matter with regard to claims 3, 12, 18, 27, 37, 40, and 43. Applicants also note that claim 9 was previously indicated to be allowable in the Office Action mailed May 21, 2003, and no rejection was made for claim 9 in the latest Office Action mailed May 5, 2004, though the latest Office Action did not expressly indicate that claim 9 was allowable.

I. EXAMINER INTERVIEW WAS INITIATED

A telephone interview was initiated with the Examiner on October 1, 2004. However, the PTO made the file unavailable to the Examiner such that a proper interview was not possible. The file was considered to be necessary for the interview to enable discussion of the prior art references of record, especially in light of Applicants' position that one of the references used in

the rejection, the Biomet reference, was improperly considered to be prior art in rejecting many of the claims. The interview was to be postponed until the Examiner could obtain the file history. However, the file history was not available to the Examiner in time for the Interview to take place. Applicants appreciate the Examiner's willingness to attempt an interview even though the interview had to be aborted.

The Examiner reported in a subsequent telephone conversation on October 26, 2004, that in light of the current move of the relevant offices to Alexandria, the file would likely not be available and a resolution of the Interview would not be possible prior to the October 5, 2004 deadline for responding to the Office Action. The Examiner recommended that the present response to the Office Action be submitted without the benefit of an Examiner interview. Applicants note with appreciation the Examiners indication that if the present response does not place the application in condition for allowance, any following Office Action would be made non-final.

II. REJECTIONS OF CLAIMS UNDER 35 U.S.C. § 112 ARE TREATED

Claims 6, 15, 30, and 40 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

The Office Action indicated that claims 6, 15, 30, and 40 do not further limit the claims from which they depend. The Office Action alleges it is not clear how the functional recitation further defines the angle as claimed. However, the language in the claims "wherein the flared plate surface forms an angle with a long axis of the stem means which is greater than ninety degrees to thereby enhance settling action of said flared plate surface against the load-bearing surface of the first bone" further defines the angle as claimed in that some ranges of angles greater than 180 degrees do not include the structure necessary to perform the function. For example, if the flared plate surface forms an angle that is 180 degrees with a long axis of the stem means, settling action of the flared plate surface against the load-bearing surface of the bone may not occur as indicated. As stated in MPEP § 2173.05(g) "a functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used." Applicants respectfully submit that the additional functional language in claims 6, 15, 30, and 40 provides adequate subject matter to further limit these claims as compared to the claims from which they depend. Accordingly, Applicants respectfully request that the rejection of claims 6, 15, 30, and 40 be withdrawn.

III. REJECTIONS OF CLAIMS UNDER 35 U.S.C. §§ 102 AND 103 ARE TREATED

Claims 1, 2, 6-8, 10, 11, 15, 16, 19-26, 30, 31-33, and 44-46 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kirshner in view of U.S. Patent No. 5,092,899 to Forte (herein the "Forte" patent). Claims 1, 2, 4-7, 11, 13-17, 24, 25, 26, 28-32, 34, 36, and 38-42 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,152,963 to Noiles (hereinafter the "Noiles" patent).

Applicants' counsel has carefully studied the reasoning for the rejection provided in the Office Action, together with the prior art references relied upon. Applicants respectfully submit in good faith that certain aspects of the invention are unanticipated, nonobvious and allowable.

Regarding the rejection of claims 1, 2, 6-8, 10, 11, 15, 16, 19-23, 25, 26, 30, 31-33, and 44-46 under 35 U.S.C. §103(a) as being unpatentable over Kirshner in view of Forte, Applicants maintain that the Office Action has improperly relied upon a reference referred to as the "Biomet" publication in making the rejection. Attached hereto as Exhibit A are color photoprints of a document understood by Applicants to be the Biomet publication. The date indicated on the Biomet reference is 1997, whereas priority date for the above referenced claims dates back to 1994. Attached hereto as Exhibit B is a photoprint of a one-page document

referred to as the Kirshner reference. The Office Action indicated that "the osteocap hip as disclosed by Kirshner and illustrated in the Biomet publication is one and the same." Applicants respectfully traverse this position. Moreover, Applicants respectfully submit that since the Office Action included the Biomet reference as part of rejections associated with the Kirshner reference, the rejection of the above claims relying on the Kirshner reference is not valid as relying upon a non-prior art reference.

Inspection of the Kirshner reference and the Biomet publication reveals various differences in the products disclosed in those documents. For example, the Kirshner product has a tapered stem, whereas the Biomet device has a non-tapered stem. Also, the configuration of the roughened surfaces are different as shown on the Kirshner product as compared to the Bioment product. Additionally, the one page Kirshner reference refers to a C-2® OSTEOCAP™ HIP, whereas the Biomet reference refers to OSTEOCAP RS™ hip system surgical technique. Accordingly, despite the common use of the term "OSTEOCAP" even the trademarks used in connection with the products are different. Thus, the product disclosed in the Biomet reference is clearly different from the product in the Kirshner reference, and since the Biomet reference is not prior art, teachings of the Biomet reference cannot be included in the Kirshner reference. Accordingly, Applicants respectfully request

that the rejection of claims 1, 2, 6-8, 10, 11, 15, 16, 19-23, 25, 26, 30, 31-33, and 44-46 as described in the Office Action under the Kirshner/Biomet reference be withdrawn.

Assuming, arguendo, the Biomet reference is excluded and only the Kirshner reference is combined with the Forte patent, Applicants respectfully submit that no motivation exists to combine these references to arrive at the subject matter claimed. For example, the abstract of the Forte patent indicates that a stem is provided having flexibility, the "flexibility therefore distributes the loading forces from the joint more uniformly over the supporting cortical bone." Also, column 4, lines 52-54 states that "It would also be advantageous to produce a prosthesis which improves the distribution of the interface reaction forces between the stem and the bone." Conversely, the Kirshner references teaches away from distributing the forces between the stem and the bone. The Kirshner references teaches a device in which "forces are not directed distally, rather they are dispersed through the collar allowing the distal stem to remain independent of these forces." Prior art references must be considered in their entirety, i.e. as a whole, including portions that teach away from the invention, and not just portions that might direct one to the invention. Panduit Corp. v. Dennison Mfg. Co., 1 U.S.P.Q.2d 1593, 1597 (Fed. Cir. 1987); Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 227 U.S.P.Q. 657, 669 (Fed. Cir. 1985) (citing

W.L. Gore & Assoc., Inc. v. Garlock Inc., 220 U.S.P.Q. 303, 311 (Fed. Cir. 1983)). It is improper to combine references where the references teach away from their combination. In re Grasselli, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983). Under these authorities, the Forte patent cannot be combined with the Kirshner reference to render any of the claims in the present application unpatentable.

Regarding the rejection of claims 1, 2, 4-7, 11, 13-17, 25, 26, 28-32, 34, 36, and 38-42 under 35 U.S.C. §102(e) as being anticipated by Noiles, the subject matter of these claims is entitled to a priority date of July 14, 1994, whereas the Noiles patent has a filing date of January 4, 1996. Accordingly, the Noiles patent is not prior art with respect to these claims and Applicants respectfully request that the rejection of these claims under Noiles be withdrawn.

Further, regarding independent claims 1, 10, 25, 34, 44, and 45, each of these claims require subject matter such as "an under surface of a terminal portion of a lip of said medial section forms an angle with the long axis of the stem means which is greater than ninety degrees." Since the Office Action clearly relied on additional disclosure that is not part of the Kirshner reference in making a rejection (the Office Action appears to have occasionally mistaken the now disqualified Biomet reference with the Kirshner reference), Applicants reiterate the position explained in the

preliminary amendment and Response A, that the Kirshner reference does not anticipate these claims. Anticipation requires a showing that "each element of the claim in issue is found, either expressly or under principles of inherency, in a single prior art reference, or that the claimed invention was previously known or embodied in a single prior art device or practice." Minnesota Mining and Manufacturing v. Johnson & Johnson, 24 U.S.P.Q 2d 1321, 1326 (Fed. Cir. 1992).

It is unknown from a reading of the Kirshner drawing what exactly would be revealed by rotating the depicted stem ninety degrees to bring the medial lip under surface into view, in contrast to applicants' disclosure which includes the clear detail of FIG. 1A and corresponding written description. Such a view, or any disclosure corresponding to it, is unavailable in the mere side-view profile drawing of Kirshner, leaving any three dimensional environment of the medial lip undersurface unknown, and subject to speculation and hindsight analysis. Regardless of the two-dimensional, side-view profile of Kirshner, the actual medial-lip under surface exists in the context of a three-dimensional environment that may comprise one of any number of structural possibilities. Without some illustration or description in Kirshner to show the three dimensional environment, as in the manner of FIG. 1A of applicants' application, it would be speculation to presume whether the angle formed between the medial

lip undersurface and the long axis of the stem would be greater than ninety degrees in the Kirshner prosthesis.

Independent claims 1, 10, 25, 34, 44, and 45 are therefore not anticipated because the Kirshner drawing does not expressly identify the subject matter "an under surface of a terminal portion of a lip of said medial section forms an angle with the long axis of the stem means which is greater than ninety degrees." The drawing would need to include something more, such as an angle symbol in reference to defined angle lines that are clearly greater than ninety degrees, or some other such specific teaching.

Furthermore, the Kirshner drawing does not expressly illustrate the multi-dimensional concept of the subject matter "an under surface of a terminal portion of a lip of said medial section forms an angle with the long axis of the stem means which is greater than ninety degrees." The Kirshner drawing is a mere profile, and does not reveal the structure of the undersurface of a terminal portion of the lip. Ex parte Levy, 17 U.S.P.Q. 2d 1461, 1462 (Bd Pat App & Inter 1990), "Moreover, it is incumbent upon the examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference."

In addition to not expressly depicting or illustrating the element in question, Kirshner also does not inherently disclose the subject matter "an under surface of a terminal portion of a lip of said medial section forms an angle with the long axis of the stem

means which is greater than ninety degrees." "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is *necessarily* present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." In re Robertson, 49 U.S.P.Q.2d 1949, 1950 (Fed. Cir. 1999) (citations omitted) (*italics added*).

Because the Kirshner reference fails to show the undersurface of the terminal portion of the lip or discuss this feature in the written text, the angle of the under surface is not necessarily present in the Kirshner reference. It is possible that the Kirshner prosthesis could contain an indentation in the undersurface of the terminal portion of the lip such that the profile would appear as pictured in the Kirshner reference, but such that the angle of the undersurface with respect to the long axis would be less than 90 degrees. The requisite angle is therefore not necessarily present as required by the above authority for inherency, so the Kirshner drawing does not inherently disclose the invention. In re Robertson, 49 U.S.P.Q.2d 1949, 1950 (Fed. Cir. 1999) (citations omitted), "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient."

Regarding obviousness, the invention of independent claims 1, 10, 25, 34, 44, and 45 is also not obvious when Kirshner is

combined with the other prior art references, since Kirshner provides no suggestion for an under surface of a terminal portion of a lip of the medial section to form an angle with the long axis of the stem means which is greater than ninety degrees. Kirshner not only fails to disclose the subject matter in diagrams or written text, but is also silent as to the advantages of an undersurface of the terminal lip forming an angle with the long axis of greater than ninety degrees. The present invention allows incremental micro-motion that permits the prosthesis to gradually, ever so slightly, settle into a position of stability (see page 13, lines 4-16 of the specification).

The Federal Circuit has repeatedly cautioned against employing hindsight by using the applicant's disclosure as a blueprint to reconstruct the claimed invention out of isolated teaching of the prior art. See, e.g., Grain Processing Corp. v. American-Maize Prods. Co., 5 U.S.P.Q.2d 1788, 1792 (Fed. Cir. 1988).

Applicants submit that this is a classic case where a reference must have some clear and specific suggestion or indication of the presence of the feature claimed, yet the Kirshner reference lacks such specificity. It is understandable that the Patent Office may initially choose to isolate certain elements in a patent and claim, with the benefit of hindsight, that the element or elements are present in the Kirshner drawing. However, in the absence of a specific suggestion, such a practice is tantamount to

the Patent Office impermissibly using applicant's teachings to hunt through the prior art references for the claimed elements and concoct them in combination without suggestion. In re Laskowski, 10 U.S.P.Q.2d 1397, 1398 (Fed. Cir. 1989). The Office must provide specific, concrete documentation of the feature in the prior art, or some suggestion thereof. See Id.

The law cited above, and other similar authority, prohibit such hindsight speculation to be relied upon for a finding of unpatentability. Indeed, it would take a retrospective view of the Kirshner drawing, in light of applicants' discovery as defined in claims 44-46, to enable one of ordinary skill to obtain the concept of the claimed subject matter "an under surface of a terminal portion of a lip of said medial section forms an angle with the long axis of the stem means which is greater than ninety degrees", an undertaking which is clearly prohibited by law. In re Newell, 13 U.S.P.Q.2d 1248, 1250 (Fed. Cir. 1989).

Accordingly, independent claims 1, 10, 25, 34, 44, and 45 are believed to be allowable, for the reasons expressed above, and the claims depending from those independent claims are also believed to be allowable.

Regarding claim 24, subject matter is required in claim 24 that is not entitled to the 1994 priority date. However, the Kirshner, the Forte and the Biomet references all fail to disclose the claimed element of the spacial posterior gap and the spacial

anterior gap. Accordingly, claim 24 is believed to be patentable over those references.

Moreover, the Noiles patent fails to disclose the claim 24 element of a slot extending along a long axis of the stem means. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegall Bros. V. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). There is no discussion of a slot in the Noiles patent, nor are there drawings of a slot or hidden lines depicting a slot. The drawings in the Noiles patent include lines depicting a fluted exterior, but Noiles provides no clear and particular suggestion of a slot. Careful inspection of the drawings in the Noiles patent, including FIG. 1, reveals that only flutes are shown in the stem of the prosthesis in the Noiles patent. The Office Action appears to assume the existence of a through slot, without actual disclosure of a slot. This amounts to speculation and an assumption of facts that are not present. Since the Noiles patent does not disclose the slot in the stem means, the Noiles patent does not anticipate claim 24. Moreover, there is no motivation to combine the Noiles patent with the other prior art of record to arrive at the subject matter of claim 24, such that claim 24 is believed to be allowable.

IV. CONCLUSION AND AUTHORIZATION OF DEPOSIT ACCOUNT

In view of the foregoing, applicants believe that claims 1-20, 24-45, 47, and 48 are all allowable and the same is respectfully requested. If any impediment to the allowance of these claims remains after entry of this Amendment, and such impediment could be alleviated during a telephone interview, the Examiner is invited to initiate the same.

The Commissioner is hereby authorized to charge any additional fee or to credit any overpayment in connection with this Amendment to Deposit Account No. 50-0836.

DATED this 5 day of November, 2004.

Respectfully submitted,



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